MedImmune, Inc. Testimony

November 17, 2004

Government Reform Committee

Good morning. My name is Dr. Kathleen Coelingh, and I am the Senior Director of Regulatory and Scientific Affairs at MedImmune, Inc, a Maryland-based biotechnology company that manufactures the innovative intranasal influenza vaccine, FluMist. Approved by the FDA last year for healthy persons 5 to 49 years of age, FluMist is the first advancement in influenza prevention in 50 years.

We are at a critical juncture in defining what the influenza vaccine market will look like in the future and how U.S. based vaccine manufacturers will meet the needs of this country going forward. What will be the incentives for companies to build U.S. based manufacturing facilities? How will our government drive vaccine acceptance, utilization, and demand – since it is demand that ultimately determines the supply of vaccine manufactured? And what will be the incentive for continued innovation?

MedImmune recommends that this committee support and encourage two key longer-term solutions in the realm of policy changes and incentives for innovation. The first recommendation is to move towards adoption of a universal recommendation for influenza vaccine for all Americans. The

current recommendations, which are based on age groups and an ever-expanding list of underlying chronic medical conditions, are both complicated for the health care provider and confusing to the public. We believe that a universal recommendation will stabilize demand for vaccine, thereby leading to increased vaccine supply, and ultimately to substantially lowering the current morbidity and mortality rates.

As an interim step, MedImmune recommends required vaccination of school-aged children, who have a very high influenza attack rate and spread influenza to younger siblings, parents, grandparents, etc. Thus, vaccination of school children would directly benefit the children themselves and may also have the potential to greatly reduce the impact of influenza in our communities. This concept of protecting an entire community by vaccinating the school-aged children has been demonstrated in Japan and in studies in the U.S. In conjunction with this interim step, money must be appropriated to expand the education of the public and the medical community about the seriousness of influenza and the value of influenza prevention.

The second solution that MedImmune recommends to ensure continued influenza vaccine supply is to provide tax incentives for scientific innovation and for construction of U.S. based facilities. MedImmune is a primary innovator in the area of molecular techniques, termed "reverse genetics." The use of reverse genetics is vital to producing seeds for an H5N1 pandemic vaccine. MedImmune owns multiple patents in this area and has granted free access to its reverse genetics intellectual property to government organizations and to other companies developing pandemic influenza vaccines. MedImmune is currently collaborating with the National Institutes of Health to produce intranasal pandemic vaccines and to test them in clinical trials.

MedImmune also has core expertise in the innovative area of cell culture manufacturing. The main advantages of manufacturing using cell culture are elimination of dependence on egg supplies and more consistent and rapid production, which will be critical in the event that the egg supply is decimated by the emergence of a pandemic virus. The transition from egg-based to cell-based manufacturing will require considerable investment in the construction of new manufacturing facilities and clinical studies. Tax incentives to subsidize the cost of such innovations are necessary to

guarantee a more stable vaccine supply on a yearly basis and when the pandemic arrives.

The government also needs to incentivize manufacturers to build manufacturing facilities in the U.S. There is an increased risk that with offshore manufacturing, companies will face political decisions that may prevent product from entering the U.S. – particularly in the event of a catastrophic pandemic. Tax incentives for U.S.-based manufacturing facilities would encourage manufacturers to build more facilities in the U.S.

To address what MedImmune has done during the current vaccine shortage, since October 5th, we have worked diligently with the appropriate authorities to:

1) Blend and fill our excess bulk vaccine to produce an additional 2 million doses of FluMist, bringing total production this year to about 3 million doses;
2) Supply the Department of Defense with 400,000 doses, the CDC with 125,000 doses, and hospitals with over 40,000 free doses and more than 200,000 commercially purchased doses.

3) Supply the FDA with new storage data for FluMist, which they promptly reviewed and approved, allowing the additional 2 million doses of FluMist to be stored in a household freezer without the requirement for a special freezer box; and
4) Work closely with CDC and ACIP to clarify that FluMist is an option for all healthy people from 5 to 49 years of age to consider if they want to protect themselves against the flu this season.

Shifting gears a bit and looking ahead to next season, you must understand that the influenza vaccine manufacturing campaign for the 2005-2006 season is starting right now. We are already preparing the new vaccine seeds for strains anticipated to be in next year's vaccine and making decisions about how many doses of vaccine we will manufacture next year, including deciding how many eggs to order. Thus, the amount of FluMist that will be available for next year will soon be fixed.

With some additional regulatory cooperation, MedImmune has the capacity to produce between 8 and 10 million doses next season. These regulatory actions include:

1) FDA approval allowing for the production of larger lot sizes and product filtration;
2) Acceptance by the FDA of our application to permanently eliminate the requirement for FluMist storage in special freezer boxes; and
3) FDA acceptance of recently submitted data that supports the expansion of the FluMist indication to include the 30 million Americans who are 50 to 64 years old, a group that is <u>not</u> eligible for the injectable flu shot this year, and may not be eligible again next year should we experience a continuing shortage.

To summarize, MedImmune is clearly at a crossroads in determining not only how much FluMist will be available next season, but also whether our investments in innovation will be recouped in this market. Our level of production for next season depends upon the occurrence of several immediate regulatory actions. But whether MedImmune expands its production and whether companies continue their efforts to develop influenza vaccines depends in large part upon the government's commitment to encouraging innovation and driving demand. Requiring childhood flu vaccinations as an interim step towards a universal recommendation and legislating tax incentives for both scientific innovation and U.S.-based

manufacturing will go a long way towards ensuring an adequate supply of influenza vaccine in the near future.

Thank you.